



Food and Drug Administration
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December 17, 2014

Reckitt Benckiser, LLC
Shahper Rahman
Regulatory Strategic Lead
Morris Corporate Center IV
399 Interpace Parkway
Parsippany, NJ 07054

Re: K131643
Trade/Device Name: Durex[®] RealFeel[™] Pleasure Gel Personal Lubricant
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: November 18, 2014
Received: November 19, 2014

Dear Shahper Rahman,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the [Federal Register](#).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-

related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Herbert P. Lerner -S

for

Benjamin R. Fisher, Ph.D.

Director

Division of Reproductive, Gastro-Renal,
and Urological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): __K131643__

Device Name: Durex ® RealFeel™ Pleasure Gel Personal Lubricant

Indications For Use:

Durex® RealFeel™ Pleasure Gel Personal Lubricant is intended for penile and/or vaginal application, intended to moisturize and lubricate, to enhance the ease of comfort of intimate sexual activity and supplement the body's natural lubrication. This lubricant is compatible with polyurethane condoms. It is not compatible with natural rubber latex and polyisoprene condoms.

Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use __X__
(21 CFR 801 Subpart C)

**(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
OF NEEDED)**

Concurrence of CDRH, Office of Device Evaluation (ODE)



510(k) Summary K131643

Submitted by:

Reckitt Benckiser, LLC
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399 Interpace Parkway
Parsippany, NJ 07054
973-404-2781

Contact Person: Shahper Rahman, Regulatory Strategic Lead, Reckitt Benckiser, LLC

Date Prepared: November 18, 2014

Proprietary Name: Durex® Personal Lubricant-Silicone

Trade Name: Durex® RealFeel™ Pleasure Gel Personal Lubricant

Common Name: Personal Lubricant

Classification Name: Condom (21CFR 884.5300)

Product Code: NUC (lubricant, personal)

Predicate Devices: ONE® Silicone Lubricant
One
510(k) Control Number: K110690

Description of Device:

Durex® RealFeel™ Pleasure Gel is a non-sterile, personal silicone base lubricant. The lubricant is comprised of cyclopentasiloxane and dimethiconol. Durex® RealFeel™ Pleasure Gel contains a blend of silicone fluid ingredients similar to ingredients found in the predicate device. The specifications for Durex® RealFeel™ Gel include appearance, odor, viscosity, specific gravity, total aerobic microbial count, total yeast and mold count, and absence of pathogenic organisms (*Pseudomonas aeruginosa*, *Staphylococcus aureus*, and *Candida albicans*).

Intended Use of the Device:

Durex® RealFeel™ Pleasure Gel Personal Lubricant is intended for penile and/or vaginal application, intended to moisturize and lubricate, to enhance the ease of comfort of intimate sexual activity and supplement the body's natural lubrication. This lubricant is compatible with polyurethane condoms. It is not compatible with natural rubber latex and polyisoprene condoms.

Comparison of Technological Characteristics with the Predicate Device

Intended Use Comparison

The table below shows the indication statements for the Durex® RealFeel™ Pleasure Gel and the predicate devices:

	Durex® RealFeel™ Pleasure Gel	ONE Silicone Lubricant
510(k) Number	K131643	K110690
Indication for Use	Durex® RealFeel™ Pleasure Gel Personal Lubricant is intended for penile and/or vaginal application and to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with polyurethane condoms. It is not compatible with natural rubber latex and polyisoprene condoms.	ONE Silicone Lubricant is an over the counter personal lubricant for penile and/or vaginal application, intended to moisturize and lubricate, to enhance the ease of comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with natural rubber latex, polyisoprene, and polyurethane condoms

The only difference in the intended use Durex® RealFeel™ Pleasure Gel in comparison to predicate device is condom compatibility. This difference does not represent a new intended use. Therefore, to the Durex® RealFeel™ Pleasure Gel and the predicate device have the same intended use.

Technological Characteristics:

The Durex® RealFeel™ Pleasure Gel contains a blend of silicone fluid ingredients similar to ingredients found in the predicate device.

The Durex® Embrace Pleasure Gels and the predicate device have the same technological characteristics.

Performance Data:

The performance data provided in the 510(k) submission are summarized below.

Biocompatibility:

Four biocompatibility studies were conducted on the subject device. The endpoints evaluated included cytotoxicity, systemic toxicity in mice, maximization sensitization in guinea pigs, and vaginal irritation in rabbits. Each study was conducted in accordance with GLP requirements and the applicable ISO 10993-1 standard. The results demonstrate that the subject device is biocompatible.

**Condom Compatibility:**

The condom compatibility testing was conducted in accordance with ASTM D7661-2010. The results demonstrate that the Durex® RealFeel™ Pleasure Gel is compatible with polyurethane condoms but is not compatible with natural rubber latex and polyisoprene condoms.

Stability:

The results of accelerated and real time studies demonstrate that the subject lubricant maintains its specifications over the duration of its shelf life.

Conclusion:

Based on the results of biocompatibility testing and nonclinical performance testing, Durex® RealFeel™ Pleasure Gel is substantially equivalent to the predicate device.